Commentary

Market Spiral Pricing of Cancer Drugs

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Every patient with cancer or another life-threatening disease wants the most effective treatment, but drug prices have become staggering. Twelve of the 13 new cancer drugs approved last year were priced above $100,000 annually (Table 1), and a 20% copayment makes them unaffordable, even for well-insured patients.[1]

What determines the escalating prices of cancer drugs? Pharmaceutical experts often cite the high research costs and the benefit or added value of the new cancer drug. We believe that neither argument is well-founded and that pharmaceutical companies may be using a third strategy: constantly raising prices on last year's drugs and then pricing new ones above the new market price level; this is known as the Market Spiral Pricing Strategy.

The industry-sponsored estimate of average research costs to get a drug to market is $1.3 billion, including the cost of failures.[2,3] Such estimates may be significantly inflated:[4]

- First, half of this industry estimate is not research costs, but a high estimate of profits that companies would have made if they had not invested in research in the first place. There are good reasons for subtracting these "profits foregone" as not real research costs, which brings the average down from $1.3 billion to $650 million.
- Second, taxpayers subsidize about half of company research through various credits and deductions (though companies make sure no one can get an accurate figure). This brings the average cost down to $325 million.
- Third, this industry estimate was made on the most costly fifth of new drugs and then misattributed to all drugs. Correcting for this brings the average down by 30%, to $230 million.
- Fourth, a few costly projects always distort the average cost; therefore one should use the median, which is 26% less than the average. The average is now down to $170 million.
- Fifth, there is no accurate estimate of basic research to discover new drugs because it varies so much; so an unverifiable high estimate was added that made up at least a third of the total. More than 84% of all basic research for discovering new drugs comes from the public, who also bear all the high risk.[5] After deducting taxpayer subsidies, companies spend only about 1.3% of revenues on basic research and the rest on developing minor variations or testing.[6] Removing that basic-research inflator brings the net median corporate research costs down to just $125 million (plus the variable costs of basic research).

Although such calculations are subject to unknown variables or factors that could alter the final estimates, the statement that "it costs $1 billion to develop a drug to market," which has been repeated so often that it is accepted as a solid truth, is in fact a significant overestimate. Andrew Witty, chief executive officer of GlaxoSmithKline, stated in a recent health care conference in London (March 2013) that the $1 billion cost to develop a drug is "one of the great myths of the industry."[7]

In the case of cancer drugs, most of the basic research and many clinical trials are paid by the National Cancer Institute and foundations, all free to companies. Further, clinical trials in cancer are smaller and shorter than trials for other diseases, so trial costs should be smaller too.[8] In sum, there is no credible evidence that the net costs of the major companies for cancer research are not lower than research costs for other drugs. Consequently, cancer drugs should be priced lower .

The added-value argument for unaffordable prices is not supported by objective data. Most new cancer drugs provide few or no clinical advantages over existing ones. Only one of the 12 new anticancer drugs approved in 2012 provides survival gains that last more than 2 months (Table 1).

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TABLE 1. Prices of Anticancer Drugs Approved by the Food and Drug Administration in 2012

Drug (Trade Name; Company)	Indication	Approval Basis	Dose	Monthly or Per-Cycle Cost
Axitinib (Inlyta; Pfizer)	Metastatic renal cell carcinoma	2-mo PFS benefit compared to sorafenib	5 mg orally twice daily (can be increased to 10 mg orally twice daily)	$10,584 (up to $21,168)/mo
Enzalutamide (Xtandi; Astellas)	Metastatic prostate cancer	5-mo OS benefit compared to placebo	160 mg orally daily	$8,940/mo
Ziv-aflibercept (Zaltrap; Sanofi-Aventis)	Metastatic colorectal cancer	1.5-mo OS benefit compared to placebo (combined with chemotherapy)	4 mg/kg IV every 2 weeks	$15,360/mo (two 200-mg vials per dose; 80 kg)
Regorafenib (Stivarga; Bayer)	Metastatic colorectal cancer	1.4-mo OS benefit compared to placebo	160 mg orally daily for 21 of 28 days	$11,220/mo
Pertuzumab (Perjeta; Genentech)	Metastatic breast cancer	6-mo PFS benefit compared to placebo (combined with chemoimmunotherapy)	420 mg IV every 3 weeks (maintenance dose)	$4,890/3 weeks
Cabozantinib (Cometriq; Exelixis)	Metastatic medullary thyroid cancer	7-mo PFS benefit compared to placebo	140 mg orally daily	$11,880/mo
Vismodegib (Erivedge; Genentech)	Basal cell carcinoma	Objective response rate	150 mg orally daily	$9,000/mo
Carfilzomib (Kyprolis; Onyx)	Multiple myeloma	Objective response rate	20 mg/m^2 on days 1, 2, 8, 9, 15, and 16 every 28 days	$11,937/mo (1.8 m^2)
Bosutinib (Bosulif; Pfizer)	Chronic myeloid leukemia	Objective response rate	500 mg orally daily	$9,817/mo
Ponatinib (Iclusig; ARIAD)	Chronic myeloid leukemia	Objective response rate	45 mg orally daily	$12,900/mo
Omacetaxine (Synribo; Teva)	Chronic myeloid leukemia	Objective response rate	1.25 mg/m^2 subcutaneously every 12 hours for 14 days per month until hematologic response	$28,056/mo for 14-day cycles; $14,028/mo for 7-day cycles (1.8 m^2)
Vincristine sulfate liposome (Marqibo; Talon)	Acute lymphoid leukemia	Objective response rate	2.25 mg/m^2 IV weekly	≈$12,000/cycle
Glucarpidase (Voraxase; BTG International)	Methotrexate toxicity	Rapid and sustained clinically important in plasma methotrexate concentration	50 units/kg	$108,000 (80 kg)

Abbreviations: IV, intravenous; OS, overall survival; PFS, progression-free survival.

Some economic experts argue that, in a free-market economy, pricing is based on "what the market will bear," which will, in the long run, settle prices at reasonable levels. However, there appears to be no free-market forces, but rather what seems to be monopoly rights to charge similarly high prices, even when several cancer drugs are available for the same cancer indication. Although 90% of oncologists state they would prescribe a cheaper drug for their patient if there are 2 drugs of similar efficacy and toxicity profiles, there are not enough drug price sensitivities (or differences) to allow oncologists or patients to select drugs based on costs savings.

In the past 5 years, companies have doubled the prices for cancer drugs, and have increased prices every year on older drugs rather than reduce them.[9] Other countries do not allow such increases.

Market spiral pricing impoverishes desperate patients, strapped taxpayers, and struggling employers. It threatens universal access to critical care for patients facing death. Congressional hearings on spiraling prices for specialist drugs, based on the myths of greater added value and unsustainable research costs, are badly needed. In fact, the dollars that companies have put into research over the past 15 years have generated 6 times more revenues.[10] Independent studies show that companies recover all costs and make a reasonable profit at Canadian and European prices, but still charge Americans twice as much or more.[4]

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 included legislation prohibiting Medicare from negotiating drug prices.[11] This legislation, probably influenced by the pharmaceutical lobby, contributed to high drug prices and, when implemented in 2006, was associated with an immediate increase in pharmaceutical company profits.[12] An analysis by Dean Baker, a well-known economist, suggested that allowing Medicare to negotiate drug prices could save $40 billion to $80 billion annually.[13] Congress should eliminate the prohibition against Medicare negotiating discount prices on drugs; this could save the health care industry billions of dollars annually and avoid a lot of grief for patients.[11,13] Congress should also prevent companies from delaying access to generic drugs, which would not only relieve millions of patients, but would also save on average $80 billion to $100 billion annually, and would foster more innovation, because patents generate more innovation by ending, not by perpetuating, monopoly pricing. Oncologists would then be able to treat their patients with drugs they can afford.

CONFLICT OF INTEREST DISCLOSURE

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